

(2) Color additive mixtures for drug use made with mica-based pearlescent pigments may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring ingested drugs.

(b) *Specifications.* Mica-based pearlescent pigments shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

(1) Lead (as Pb), not more than 4 parts per million (ppm).

(2) Arsenic (as As), not more than 3 ppm.

(3) Mercury (as Hg), not more than 1 ppm.

(c) *Uses and restrictions.* Mica-based pearlescent pigments may be safely used to color ingested drugs in amounts up to 3 percent, by weight, of the final drug product. The maximum amount of iron oxide to be used in producing said pigments is not to exceed 55 percent, by weight, in the finished pigment.

(d) *Labeling.* The label of the color additive and of any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act.

[70 FR 42273, July 22, 2005. Redesignated at 72 FR 10357, Mar. 8, 2007]

#### § 73.1375 Pyrogallol.

(a) *Identity.* The color additive pyrogallol is 1,2,3-trihydroxybenzene.

(b) *Specifications.* Pyrogallol shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Melting point, between 130° and 133 °C.

Residue on ignition, not more than 0.1 percent.

Lead (as Pb), not more than 20 p/m (parts per million).

Arsenic (as As), not more than 3 p/m.

(c) *Uses and restrictions.* Pyrogallol may be safely used in combination with ferric ammonium citrate (as listed in § 73.1025), for coloring plain and chromic catgut sutures for use in general and ophthalmic surgery, subject to the following restrictions:

(1) The dyed suture shall conform in all respects to the requirements of the United States Pharmacopeia XX (1980).

(2) The level of the ferric ammonium citrate-pyrogallol complex shall not exceed 3 percent of the total weight of the suture material.

(3) When the sutures are used for the purposes specified in their labeling, there is no migration of the color additive to the surrounding tissues.

(4) If the suture is a new drug, an approved new drug application, pursuant to section 505 of the act, is in effect for it.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 49 FR 10089, Mar. 19, 1984]

#### § 73.1400 Pyrophyllite.

(a) *Identity.* (1) The color additive pyrophyllite is a naturally occurring mineral substance consisting predominantly of a hydrous aluminum silicate,  $\text{Al}_2\text{O}_3 \cdot 4\text{SiO}_2 \cdot \text{H}_2\text{O}$ , intimately mixed with lesser amounts of finely divided silica,  $\text{SiO}_2$ . Small amounts, usually less than 3 percent, of other silicates, such as potassium aluminum silicate, may be present. Pyrophyllite may be identified and semiquantitatively determined by its characteristic X-ray powder diffraction pattern and by its optical properties.

(2) Color additive mixtures made with pyrophyllite are limited to those listed in this subpart as safe and suitable in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* Pyrophyllite shall conform to the following specifications:

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Lead (as Pb), not more than 20 parts per million.  
Arsenic (as As), not more than 3 parts per million.

Lead and arsenic shall be determined in the solution obtained by boiling 10 grams of the pyrophyllite for 15 minutes in 50 milliliters of 0.5N hydrochloric acid.

(c) *Uses and restrictions.* Pyrophyllite may be safely used in amounts consistent with good manufacturing practice to color drugs that are to be externally applied.

(d) *Labeling requirements.* The labeling of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of §70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

### §73.1410 Logwood extract.

(a) *Identity.* The color additive logwood extract is a reddish brown-to-black solid material extracted from the heartwood of the leguminous tree *Haematoxylon campechianum*. The active colorant substance is principally hematein. The latent coloring material is the unoxidized or leuco form of hematein called hematoxylin. The leuco form is oxidized by air.

(b) *Specifications.* Logwood extract shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Volatile matter (at 110 °C), not more than 15 percent.  
Sulfated ash, not more than 20 percent.  
Hematein, not less than 5 percent and not more than 20 percent.  
Lead (as Pb), not more than 70 parts per million.  
Arsenic (as As), not more than 4 parts per million.  
Mercury (as Hg), not more than 3 parts per million.

(c) *Use and restrictions.* Logwood extract may be safely used to color nylon 66 (the copolymer of

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hexamethylenediamine and adipic acid), nylon 6 (the polymer of *ε*-caprolactam), or silk non-absorbable sutures for use in general and ophthalmic surgery subject to the following restrictions:

(1) The quantity of color additive does not exceed 1.0 percent by weight of the suture.

(2) When the sutures are used for the purposes specified in their labeling, there is no migration of the color additive to the surrounding tissue.

(3) If the suture is a new drug, an approved new drug application, pursuant to section 505 of the act, is in effect for it.

(d) *Labeling.* The label of the color additive shall conform to the requirements of §70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

[42 FR 52393, Sept. 30, 1977; 43 FR 1490, Jan. 10, 1978]

### §73.1496 Mica.

(a) *Identity.* (1) The color additive mica is a white powder obtained from the naturally occurring mineral, muscovite mica, consisting predominantly of a potassium aluminum silicate,  $K_2Al_4(Al_2Si_6O_{20})(OH)_4$  or, alternatively,  $H_2KAl_3(SiO_4)_3$ . Mica may be identified and semiquantitatively determined by its characteristic X-ray diffraction pattern and by its optical properties.

(2) Color additive mixtures for drug use made with mica may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications.* Mica shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Fineness, 100 percent shall pass through a 100-mesh sieve.  
Loss on ignition at 600–650 °C, not more than 2 percent.  
Lead (as Pb), not more than 20 parts per million.  
Arsenic (as As), not more than 3 parts per million.